

Remarks

Claims 1, 6, and 9 remain pending in this application. Claims 1 and 6 have been amended. Claim 1 has been amended to reflect compliance with the restriction requirement. Basis for further amendment to Claim 1 can be found in the specification on page 26, lines 8 through 28, and on page 27, lines 1 through 13. Basis for the amendment to Claim 6 can be found in the specification on page 194 at lines 7 to 13. New Claims 11 and 12 have been entered and add no new matter. Basis for Claim 11 can be found on page 26 of the specification at line 16. Basis for claim 12 can be found on page 26 of the specification at line 18.

Response to Election/Restriction

The Examiner has made the restriction requirement of January 23, 2009 final. Applicants do not agree with the restriction requirement of Groups I and II. However, in an effort to further the prosecution of the current application, Applicants affirm the election of Group I.

Additionally, Examiner has withdrawn Claim 9 from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants point out that the present application is an international application which has entered the U.S. national stage under 35 U.S.C. § 371. As noted in MPEP § 1893.03, once the national stage application has been taken up by the examiner, prosecution proceeds under unity of invention as under 37 CFR § 1.475 – not restriction practice. Therefore, Applicants respectfully submit that the restriction of Claim 9 under unity of invention practice is improper and respectfully request reconsideration of the restriction requirement.

Applicants further direct Examiner's attention to Annex B of the Administrative Instructions Under the Patent Cooperation Treaty, Section (e), pages 64 and 65, a copy of which is attached to this response for the Examiner's convenience. The cited section provides guidance for determining the unity of invention under Rule 13.2 and in particular, the inclusion of certain combinations of claims of different categories in the same international application, specifically: "an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product[.]". This is the same scenario presented by the present application: Applicants have claimed a compound of formula I (the product) and a method of using a compound of formula I (the use of the product). As such, there is unity of invention and Claim 9 must be examined with the other pending claims of the present application.

Therefore, Applicants assert that Claim 9 has been improperly restricted. Applicants respectfully request that Examiner remove the restriction requirement from this claim and

examine all remaining claims together.

Double Patenting

The Examiner has provisionally rejected Claims 1 and 6 on the ground of nonstatutory obviousness-type double patenting over Claims 2, 8, and 13 of co-pending Application No. 10/599,129. The Examiner states:

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2, 8, and 13 in the copending application recite identical definitions and limitations for R¹ and R², and further provides definitions and limitations for R³, where R³ is pyrrolidin-2-yl, which provides homologous subject matter with respect to the substituted piperidin-2-yl and pharmaceutical compositions of formula I in the instant claims.

Office Action dated March 17, 2009, page 3-4. Furthermore, the Examiner cited MPEP § 2144.09 which states that “[c]ompounds which are . . . homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.” MPEP § 2144.09.

Because no claims have yet been issued in either of the co-pending applications, Applicants assert that the provisional nonstatutory obviousness-type double patenting rejection is premature at this time. Withdrawal of this rejection and allowance of the claims are respectfully requested.

Claim Rejections – 35 USC § 103

The Examiner has rejected claims 1 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Cumming *et. al.* (WO 05/016876). Applicants assert that Claims 1 and 6 are not obvious in light of WO 05/016876.

In order to determine whether an invention is obvious under 35 U.S.C. § 103, it is necessary to: (1) determine the scope and the contents of the prior art; (2) determine the differences between the prior art and the claims at issue; and (3) resolve the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). “[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Takeda Chemical Industries Ltd. V. Alphapharm Pty, Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). Further, the proposed modification of the prior art must demonstrate a reasonable expectation of success as determined from the vantage point of the skilled artisan at the time the invention was made and the prior art reference or combination of references must

teach or suggest all the limitations of the claims. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

Claim 1 of the present application encompasses compounds of the following formulae:

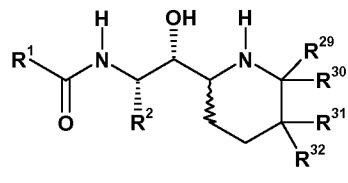


Figure (1)

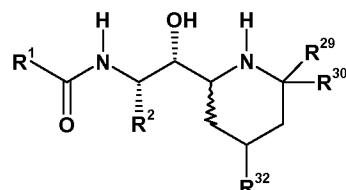


Figure (2)

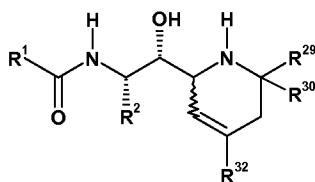


Figure (3)

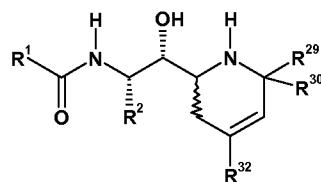


Figure (4)

WO 05/016876 exemplifies the following species relied upon by the Examiner:

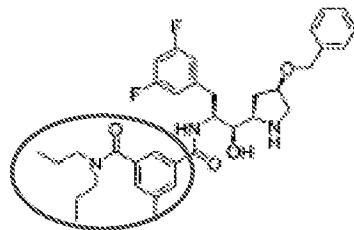


Figure (6)

First, Applicants direct Examiner's attention to the amendment made to Claim 1. The amendment is significant to the rejection under 35 U.S.C. § 103(a). The amendment eliminates the possibility that compounds of the present invention can include a substituted aryl moiety such as the moiety circled in red in Figure (6) above from WO 05/016876.

As such, to arrive at the compounds within the present application, the prior art must motivate the skilled artisan to both select the above compound, Figure (6), as a starting point for modification and then suggest the modification: to replace the substituted aryl moiety, shown circled in red in Figure (6) above, and replace it with C₁-C₆ alkyl. As a threshold matter, the Examiner has not stated why the skilled artisan would select the species of WO 05/016876, represented by Figure (6) above, as a starting point for modification. This failure alone is sufficient to defeat a finding of *prima facie* obviousness. Additionally, there is no suggestion in WO 05/016876 that would lead a skilled artisan to make the substitution at the R¹ position. Furthermore, due to the unpredictability of the art, replacing an aryl substituent on a molecule with an alkyl substituent will not lead a skilled artisan to expect a "predictable" result or an

expectation of success. Therefore, Applicants assert that a *prima facie* case of obviousness has not been established. Applicants respectfully request withdrawal of the rejection and allowance of the claims.

In summary, Applicants have amended Claims 1 and 6 and have added Claims 11 and 12. Based on the comments provided above, Applicants request that Examiner remove the restriction of Claim 9 and examine all remaining claims together. Applicants further assert that the provisional nonstatutory obviousness-type double patenting rejection is inappropriate at this time. Furthermore, Applicants assert that a *prima facie* case of obviousness has not been established. Therefore, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

Respectfully submitted,

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Attachment:

Annex B of the Administrative Instructions Under the Patent Cooperation Treaty